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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,653	09/23/2003	Christophe Carola	MERCK-2753	9118
23599	7590	10/18/2007	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			CHONG, YONG SOO	
		ART UNIT	PAPER NUMBER	
		1617		
		MAIL DATE		DELIVERY MODE
		10/18/2007		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,653	CAROLA ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 August 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-11 and 18-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 8/13/2007. Claim(s) 19-20 have been added. Claim(s) 1-20 are pending. Claim(s) 1 has been amended. Claim(s) 12-17 have been withdrawn. Claim(s) 1-11, 18-20 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below as a result of the claim amendments. Applicant's amendments have also necessitated the following new rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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There is no support in Applicant's disclosure of a specific embodiment of a compound of formula I where R¹⁻³ and R⁵⁻⁶ are simultaneously OH, therefore this compound cannot be specifically excluded from the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim(s) 1-9, 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenbloom (US Patent 6,753,325 B2).

Rosenbloom discloses a method for preventing, reducing, or treating radiation dermatitis by administering a composition comprising a compound that regulates cell differentiation and proliferation, one or more antioxidants, flavonoids, and a pharmaceutical acceptable carrier (abstract), such as ethanol (col. 7, lines 39). Preferred antioxidants include vitamin C, vitamin E (tocopherol) acetate and luteolin (col. 4, lines 54-58), particularly the flavonoids, 6-hydroxy-luteolin (col. 6, line 17) and quercetin (col. 6, line 37), which can be used in an amount of 0.02 to 2 grams per gram of the antioxidant in the composition (col. 7, lines 1-7). The examples (Tables 1-6) show antioxidants, quercetin, rutin, and luteolin, in a composition and in an amount that

meets the limitation of 0.01 to 20% by weight. The composition may be formulated into a cream, ointment, lotion (emulsion), paste, jelly (col. 7, lines 21-33) and may contain UV blockers or filters (col. 8, line 26).

It is noted that the limitations regarding cosmetic application, nutritional supplement, and protection of body cells against oxidative stress are given little patentable weight since they are preamble to a composition claim.

It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Examiner notes that the limitations regarding "wherein the at least one compound of the formula I combines anti-oxidant and UV absorption properties" will be given little patentable weight since a compound and its properties are inseparable or inherent.

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 10 is rejected under 35 U.S.C. 103(a) as being obvious over Rosenbloom (US Patent 6,753,325 B2) in view of Ley (US Patent 6,265,611 B1).

The instant claims are directed to a composition comprising a compound of formula I, an antioxidant, and a UV filter.

Rosenbloom teach as discussed above, however, fail to disclose the specifically claimed UV filters.

Ley gives the general teaching that 3-(4-methylbenzylidene)-dl-camphor is a UV filter (col. 5, lines 1-11), which is used in an antioxidant composition (abstract).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use the specific UV filter, 3-(4-methylbenzylidene)-dl-camphor, disclosed by Ley, in the antioxidant composition disclosed by Rosenbloom.

A person of ordinary skill in the art would have been motivated to do this because: (1) Ley gives the general teaching that 3-(4-methylbenzylidene)-dl-camphor is a UV filter and (2) both Rosenbloom and Ley teach the use of UV filters in an antioxidant composition. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in formulating an antioxidant composition comprising a compound of formula I, an antioxidant, and a UV filter (3-(4-methylbenzylidene)-dl-camphor) for a method for preventing, reducing, or treating radiation dermatitis.

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Claim(s) 11 is rejected under 35 U.S.C. 103(a) as being obvious over Ley (US Patent 6,265,611 B1) in view of Rosenbloom (US Patent 6,753,325 B2).

The instant claims are directed to a food composition comprising a compound of formula I.

Ley discloses an antioxidant composition for use in foods and cosmetics (abstract). Among the components of the antioxidant composition, flavonoids with antioxidant properties such as tocopherols, vitamin E, vitamin C, vitamin A, preservatives, and emulsifiers are present (col. 4, lines 15-49).

Rosenbloom gives the general teaching that the flavonoid, 6-hydroxy-luteolin, possesses antioxidant properties (col. 6, line 17),

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to use the specific antioxidant, 6-hydroxy-luteolin, disclosed by Rosenbloom, in the food composition disclosed by Ley.

A person of ordinary skill in the art would have been motivated to do this because: (1) Ley teaches the use of flavonoids with antioxidant properties in food compositions and (2) Rosenbloom gives the general teaching that the flavonoid, 6-hydroxy-luteolin, possesses antioxidant properties. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in formulating food composition comprising 6-hydroxy-luteolin.

Response to Arguments

Applicant argues that Rosenbloom does not disclose an embodiment of 6-hydroxy-luteolin since it is among a list of 96 compounds. Therefore, there is no specific evidence to suggest that Rosenbloom was in possession of a composition containing this compound.

This is not persuasive because Rosenbloom clearly teaches 6-hydroxy-luteolin as an antioxidant in a composition with a pharmaceutically acceptable carrier. Whether a long list of compounds is present or not, the fact remains that the specific compound, 6-hydroxy-luteolin, and not a broad genus, was disclosed.

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. *35 U.S.C. 282 Presumption of Validity*

Applicant argues that Rosenbloom fails to disclose a compound that "combines anti-oxidant and UV absorption properties." Applicant also argues that Rosenbloom fail to disclose the claimed percentage amounts relative to the composition as a whole. Applicant argues that Rosenbloom provides only a remote generic disclosure of the optional use of unspecified UV blockers. Finally, Applicant argues that Rosenbloom does not teach the compositions in emulsion form or with a cosmetic carrier.

This is not persuasive because Applicant has misinterpreted or failed to totally understand the Rosenbloom reference. Firstly, as mentioned in the rejection, properties such as anti-oxidant and UV absorption properties are inherent to a compound especially a flavonoid. Secondly, Rosenbloom teaches that the antioxidants can be used in the amounts of 1 to 50 grams per kg of the composition. Specifically, the examples (Tables 1-6) show antioxidants, quercetin, rutin, and luteolin, in a composition and in an amount that meets the limitation of 0.01 to 20% by weight. Thirdly, claim 9, which is rejected under the 102(e) rejection, only states "further comprising one or more UV filters," which is sufficiently met in the Rosenbloom reference especially considering the fact that the claim does not recite a specific UV filter. Lastly, one of ordinary skill in the art knows that a lotion is a type of emulsion and that a pharmaceutically acceptable carrier can also be a cosmetic carrier in light of the fact that the instant claims lack specific examples of cosmetic carriers.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



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SUPERVISORY PATENT EXAMINER